

FIELD SAFETY NOTICE (Ref. : FRA-1023)

Subject	SHORT CIRCUITING POWER SUPPLY UNIT DC CONNECTOR
Date	January 10th, 2020
Affects	PSPIX (first generation) Digital imaging plate scanner
Legal Manufacturer	SOPRO
Internal identification	FRA-1023

Dear Sopro Customer,

Sopro has identified an issue with PSPIX (first generation), *Digital imaging plates scanner*. According to our records, we have delivered to you one or more devices belonging to the serial number range defined in the table below. The Power Supply Unit (PSU) delivered with the device may have a fault requiring correction.

Product	SN range begins	SN range ends
Sopro PSPIX	OJ1208174	OJ1314402

Devices falling into these serial number ranges were delivered with PSU's having nine-digit serial numbers beginning with four digits as follows:

1143XXXXX

1221XXXXX

1224XXXXX and

1229XXXXX

Please Note: If the PSU serial number does not begin with 1143, 1221, 1224, or 1229, then no action is required.

Issue Description

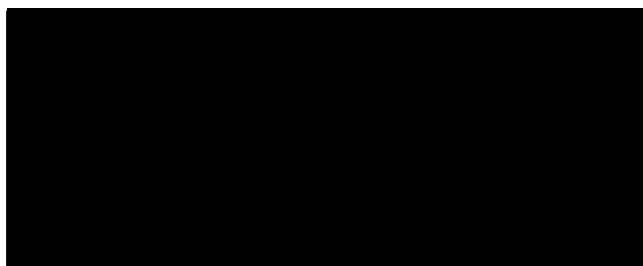
Slow degradation of plastic insulation used in the PSU DC plug may result in short circuiting which may cause heating and melting. The melting may generate smoke and eventually cause the PSU to fail. Risk of fire or injury has been assessed to be low. As a result, Sopro is being proactive with our customers to have these identified Imaging Plates Systems (IPS) corrected.

Appendix 1 consists of step-by-step instructions to identify and replace a potentially failing PSU.

Please communicate this information to your local distributors and report the initiated Medical Device Correction to your local authorities if the local regulation requires distributors to do so. Sopro as a manufacturer of the Imaging Plates Systems will take care of manufacturer's reporting to the relevant authorities.

Sopro sincerely apologizes for the inconvenience this situation causes you and your customers. If you have any questions regarding this field action, please call Kim Rouahi at +33 442 980 101 or e-mail kim.rouahi@acteongroup.com

Sincerely,



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Appendix 1

Step by step instructions to identify and change a potentially failing PSU

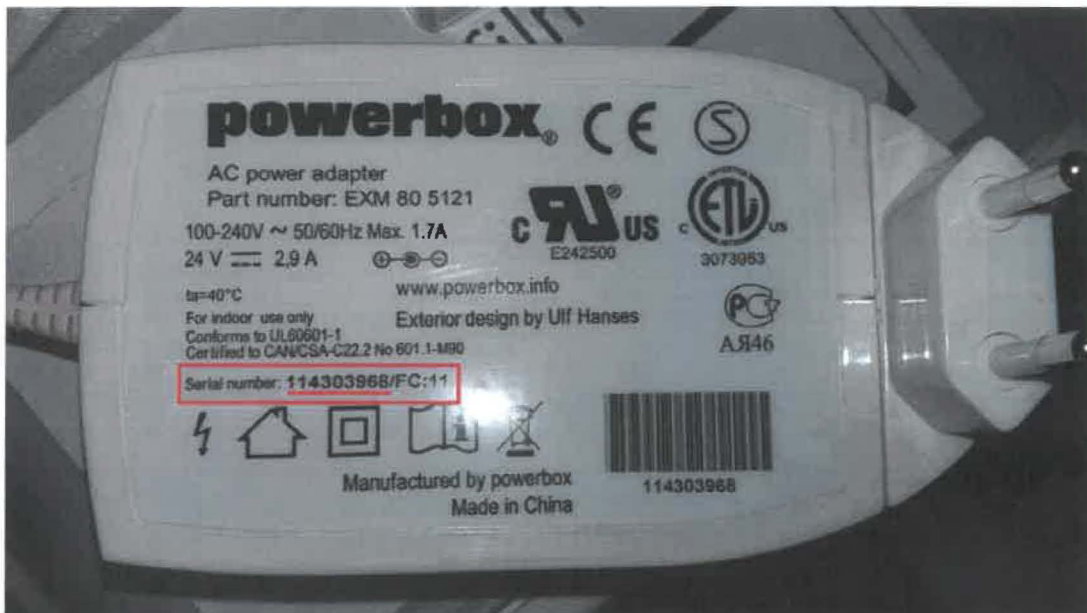
How to identify potentially failing IPS or PSU

The affected IPS unit can be identified by looking at the serial number on the scanner display or the type label at the back of the unit as shown in Picture 1.



Picture 1: The serial number of the IPS unit is located on its type label at the back of the unit.

Please locate the PSU serial number on the label shown in Picture 2.



Picture 2: The serial number of the PSU is located on its type label.

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Corrective and preventive actions

Sopro is proactively requesting you to do the following actions:

- Identify the affected devices according to the instructions above
- If the PSU serial number is within the range informed above, please contact Quality and Regulatory Assistant *Océane Mongour* for the delivery of replacement PSU free of charge. He can be reached by regular email as follows
Mrs Océane MONGOUR
SOPRO, ZAC Athélia IV, Avenue des Genévriers, 13705 La Ciotat cedex, France
Phone: +33 442 980 101
Email: oceane.mongour@acteongroup.com
- Unplug the PSU and replace it with the new one
- Dispose of the old PSU as Electronic Waste according to the local regulatory requirements.
- Send attached Confirmation Letter (Appendix 2) with your signature to oceane.mongour@acteongroup.com after performing the PSU replacement and disposing of the old PSU.
- You can provide information for several replacements made during one month in one Confirmation Letter
- The replacement shall be done for all the IPS devices / PSU units which are within the serial number range during the next 12 months.

We regret the inconvenience caused by this issue. Please contact the undersigned in case you need more information.

Sincerely,

[Redacted Signature]

Océane Mongour
Quality and Regulatory Assistant
Sopro, France
oceane.mongour@acteongroup.com

Appendix 2

Confirmation Letter

We _____ (customer name) confirm that, we have upgraded the following IPS (Imaging Plate System) with a new PSU (Power Supply Unit) and disposed of the old PSU according to instructions provided by Sopro:

Date: _____

IPS serial number(s): _____

PSU serial number(s): _____

Customer's representative signature: _____

Customer's representative name: _____

Please return fulfilled confirmation letter back to Sopro by mail or email once all the devices have been modified as requested.

RETURN TO:

Oceane MONGOUR

oceane.mongour@acteongroup.com

